



U.S. Department of Justice

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Clerk's Office
USDC, Mass.

Date 10-16-01

United States Attorney
District of Massachusetts

By ES
Deputy Clerk

1 Courthouse Way, Suite 9200
Boston, Massachusetts 02210

September 28, 2001

Daniel E. Reidy, Esquire
Jones, Day, Reavis & Pogue
77 West Wacker
Chicago, Illinois 60601

Joseph F. Savage, Jr., Esquire
Testa Hurwitz & Thibault, LLP
125 High Street
Boston, MA 02110

Re: TAP Pharmaceutical Products Inc.

Dear Mr. Reidy and Mr. Savage:

This letter sets forth the Agreement between the United States Department of Justice and the United States Attorney for the District of Massachusetts (the "U.S. Attorney") (collectively, the United States Department of Justice and the U.S. Attorney referred to as the "United States"), and your client, TAP Pharmaceutical Products Inc., and its subsidiaries ("TAP"), a Delaware corporation, (collectively referred to as "the Parties") as follows:

1. Change of Plea

On or before September 26, 2001, or such other date as the Court may set, TAP shall waive indictment and plead guilty to the Information attached hereto as Exhibit A, which Information charges TAP with a conspiracy to violate Title 21 United States Code Sections 333(b) and 331(t), by causing the sale of drug samples, all in violation of Title 18 United States Code Section 371. TAP expressly and unequivocally admits that it knowingly, intentionally and willfully committed the crime charged in the attached information.

2. Sentencing Guidelines

The United States and TAP agree that the following provisions of the United States Sentencing Guidelines ("U.S.S.G.") apply to sentencing of TAP with respect to the Information:

- (a) as indicated at the end of this section on the Sentencing Guidelines, pursuant to U.S.S.G. § 8C2.4(a) and 18 U.S.C. § 3571(d) the loss to the United States

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from this offense for criminal sentencing purposes is \$145,000,000;

- (b) pursuant to U.S.S.G. § 8C2.5, the culpability score is 8, calculated as follows:
 - (1) base score of 5 pursuant to § 8C2.5(a);
 - (2) add 4 points pursuant to § 8C2.5(b)(2)(A)(i) and/or (ii);
 - (3) deduct 1 point pursuant to § 8C2.5(g)(3).
- (c) pursuant to § 8C2.6, the applicable range for a multiplier is 1.6 to 3.2, and the appropriate multiplier to be applied as to TAP is 2.0.
- (d) the Parties agree that there is no basis for a departure under the Sentencing Guidelines, either upward or downward.

The United States represents and for purposes of this Plea Agreement, TAP does not object that, pursuant to U.S.S.G. § 8C2.4(a) and 18 U.S.C. § 3571(d), the loss to the United States from this offense for criminal sentencing purposes is \$145,000,000. TAP and the United States both acknowledge that the loss figure cannot be determined with precision and that the loss figure of \$145,000,000 for criminal sentencing purposes is an estimate.

3. Agreed Disposition

The United States and TAP agree pursuant to Fed. R. Crim. P. 11(e)(1)(C) that the following sentence is the appropriate disposition of the Information:

- (a) a criminal fine in the amount of two hundred ninety million dollars, (\$290,000,000), to be paid within fourteen days of sentencing; and
- (b) a mandatory special assessment of \$400 pursuant to 18 U.S.C. § 3013, which shall be paid to the Clerk of Court on or before the date of sentencing.

In light of the pending civil actions, United States ex rel. Douglas N. Durand v. TAP Holdings Inc., Civil Action No. 00-12618-GAO (D. Mass.), and United States ex rel. Joseph Gerstein and Tufts Health Maintenance Organization, Inc. v. TAP Holdings Inc. and TAP Pharmaceuticals Inc., Civil Action No. 98-10547-GAO (D. Mass.), and the Civil Settlement Agreement between TAP and others and the United States relating to the civil actions which is being signed contemporaneous with this Plea Agreement (the "Civil Settlement Agreement"), the parties agree that the complication and prolongation of the sentencing process that would result from an attempt to fashion a proper restitution order outweighs the need to provide restitution to the victims in this case, where, as here, the loss suffered by each of the federal health care programs will be recompensed fully from amounts paid as part of the Civil Settlement Agreement. See, 18 U.S.C. §

3663(a)(1)(B)(ii). Therefore, the United States agrees that it will not seek a separate restitution order as to TAP as part of the resolution of the Information and the Parties agree that the appropriate disposition of this case does not include a restitution order.

4. No Further Prosecution of TAP

The United States agrees that, other than the charge in the attached Information, it shall not further prosecute TAP as follows:

- (a) for conduct which falls within the scope of the conspiracy which is charged in the Information;
- (b) for conduct falling within the scope of the grand jury investigation conducted by the U.S. Attorneys in Massachusetts and in Connecticut of conduct by TAP with respect to (1) the marketing, sale, and pricing of the drug Lupron in all of its dose forms for the treatment of prostate cancer, (2) the resale by physicians and others of those drugs to the Medicare, Tricare, Railroad Retirement Medicare and state Medicaid programs; (3) TAP's contractual obligations to the state Medicaid Programs regarding reporting of "best price"; (4) provision of remuneration in cash or in kind to customers to induce the purchase or prescription of, or the recommendation to anyone that they purchase or prescribe, the drug Lupron for the treatment of prostate cancer; and (5) violation of any provision of the Prescription Drug Marketing Act in the marketing and sale of the drug Lupron in all of its dose forms;
- (c) for conduct not otherwise described in this paragraph which was known to the U.S. Attorneys in Massachusetts or Connecticut prior to the date of execution of this letter and which concerned either the sale and marketing of the drug Lupron in all of its dose forms or the sale and marketing of the drug Prevacid.

The United States does not decline criminal prosecution of TAP, Abbott Laboratories, or Takeda Chemical Industries, Ltd., or any of those corporations' related entities for any other conduct beyond that specifically described above, including, but not limited to, conduct involving the manufacture, sale or marketing to anyone of any other pharmaceutical product.

The U.S. Attorney expressly reserves the right to prosecute any individual, including but not limited to present and former officers, directors, employees and agents of TAP, in connection with the conduct encompassed by this Plea Agreement or within the scope of the grand jury investigation.

This declination is contingent on (1) the guilty plea of TAP being accepted by the Court, and not withdrawn, and (2) upon TAP's performance of all of its obligations as set forth in this Agreement, the attached Civil Settlement Agreement, the attached Side Letter Agreements with

Abbott Laboratories and Takeda Chemical Industries, Ltd., and the attached agreement regarding the limited waiver of the attorney-client privilege (which agreement shall be referred to in this Plea Agreement as the "Limited Privilege Waiver Letter"). If TAP's guilty plea is not accepted by the court or is after acceptance withdrawn for any reason, or if TAP or a related entity should fail to perform an obligation under any of these agreements, this declination of prosecution shall be null and void. The United States may, at its sole option, be released from its commitments under this Agreement, including, but not limited to, its agreement that paragraph 3 constitutes the appropriate disposition of this case, if at any time between its execution of this Agreement and sentencing, TAP:

- (a) Fails to admit a complete factual basis for the plea;
- (b) Fails to truthfully admit its conduct in the offenses of conviction;
- (c) Falsely denies, or frivolously contests, relevant conduct for which TAP is accountable under U.S.S.G. § 1B1.3;
- (d) Gives false or misleading testimony in any proceeding relating to the criminal conduct charged in this case and any relevant conduct for which TAP is accountable under U.S.S.G. § 1B1.3;
- (e) Engages in acts which form a basis for finding that TAP has obstructed or impeded the administration of justice under U.S.S.G. § 3C1.1; and/or
- (f) Attempts to withdraw its plea.

TAP expressly understands that it may not withdraw its plea of guilty, unless the Court rejects this Agreement under Fed. R. Crim. P. 11(e)(4).

5. Payment of Mandatory Special Assessment

TAP agrees to pay the mandatory special assessment to the Clerk of the Court on or before the date of sentencing.

6. Cooperation

TAP agrees to cooperate completely and truthfully with the U.S. Attorney in connection with his on-going investigation and prosecution of others for alleged violations of federal criminal law arising out of his investigation. TAP understands and agrees that such cooperation shall include the following, if requested by the U.S. Attorney:

- (a) prompt production to the U.S. Attorney of any document or record in the possession, custody or control of TAP relating to the subject matter of the investigation;

- (b) taking all reasonable measures available to TAP to ensure that present and former officers, directors, agents and employees of TAP cooperate truthfully and completely with the U.S. Attorney in connection with his on-going investigation and prosecutions; and
- (c) taking all reasonable measures available to TAP to make all present and former officers and employees of TAP available for interviews by law enforcement personnel, upon reasonable notice.

Provided, however, notwithstanding any provision of this agreement, that: (1) TAP is not required to request of its present or former officers, directors, employees or agents that they forego seeking the advice of an attorney nor that they act contrary to that advice; (2) TAP is not required to take any action against its officers, directors, employees, or agents for following their attorney's advice; and (3) TAP is not required to waive any privilege or claim of work product, except to the extent required in the previously signed Limited Privilege Waiver Letter.

7. Probation Department Not Bound By Agreement

The sentencing disposition agreed upon by the parties and their respective calculations under the Sentencing Guidelines are not binding upon the United States Probation Office. TAP's plea will be tendered pursuant to Fed. R. Crim. P. 11(e)(1)(C). TAP cannot withdraw its plea of guilty unless the sentencing judge rejects this Agreement or fails to impose a sentence consistent herewith. If the sentencing judge rejects this Agreement, this Agreement shall be null and void at the option of either the United States or TAP, and the United States will promptly return all documents (and all copies thereof) which were provided by TAP to the United States pursuant to the Limited Privilege Waiver Letter. In this regard, TAP hereby waives any defense to any charges which it might otherwise have under any statute of limitations or the Speedy Trial Act and agrees that the time relevant to any defense it might have under the statute of limitations is tolled beginning with the effective date of this Agreement and continuing until this Agreement is no longer in full force and effect.

TAP intends to seek a sentencing by the District Court immediately following the Rule 11 plea hearing. The United States does not object to the Court proceeding to sentence TAP immediately following the Rule 11 plea hearing or in the absence of a Presentence Report in this case. TAP understands that the decision whether to proceed immediately following the plea hearing with the sentencing proceeding, and to do so without a Presentence Report, is exclusively that of the United States District Court.

8. Civil Liability

TAP's civil liability to the United States in connection with the matters under investigation by the United States, as set forth in paragraph 4(a), 4(b), and 4(c) of this agreement, is resolved as set forth in the attached Civil Settlement Agreement, according to the terms set forth in that agreement.

9. Withdrawal of Plea by TAP

Should TAP move to withdraw its guilty plea at any time, this Agreement shall be null and void at the option of the U.S. Attorney.

10. Breach of Agreement

If the U.S. Attorney determines that TAP has failed to comply with any material provision of this Agreement, the United States may, at its sole option, be released from its commitments under this Agreement in their entirety by notifying TAP, through counsel or otherwise, in writing. The United States may also pursue all remedies available to it under the law, irrespective of whether it elects to be released from its commitments under this Agreement. TAP recognizes that no such breach by it of an obligation under this Agreement shall give rise to grounds for withdrawal of its guilty plea. TAP understands that, should it breach any provision of this agreement, the U.S. Attorney will have the right to use against TAP before any grand jury, at any trial or hearing, or for sentencing purposes, any statements which may be made by it and any information, materials, documents or objects which may be provided by it to the government subsequent to this Agreement, without any limitation. Provided, however, that any use by the government of the materials or information received by the government as a result of the Limited Privilege Waiver Letter shall be limited only by the terms of that letter. In this regard, TAP hereby waives any defense to any charges which it might otherwise have under the Speedy Trial Act and agrees to a tolling of the statute of limitations beginning on the date this agreement becomes effective and continuing until this agreement is no longer in full force and effect.

TAP understands and agrees that this 11(e)(1)(C) plea agreement and its agreed upon criminal disposition:

- (1) are wholly dependent upon TAP's timely compliance with the provisions of the attached Civil Settlement Agreement, including the requirement in that agreement that TAP pay to the United States and to the various state Medicaid Programs the amount of five hundred eighty-five million dollars (\$585,000,000) within thirty days of the date of execution of this plea agreement ; and that
- (2) failure by TAP to comply fully with the terms of either this agreement, the attached Civil Settlement Agreement, or the attached Limited Privilege Waiver Letter, will constitute a breach of this plea agreement.

In the event that TAP at any time hereafter breaches any material provision of this plea agreement, TAP understands that (1) the United States will as of the date of that breach be relieved of any obligations it may have in this agreement, the attached Civil Settlement Agreement, the attached Limited Privilege Waiver Letter, or the attached Side Agreements with Abbott Laboratories and Takeda Chemical Industries, Ltd., including but not limited to the promise not to further prosecute

TAP, as set forth in paragraph 4 of this plea agreement, and the promise not to prosecute Abbott Laboratories or Takeda Chemical Industries, Ltd., as set forth in the Side Agreements with both of those entities; and (2) TAP will not be relieved of its obligations to make the payments set forth in this plea agreement and in the attached Civil Settlement Agreement, nor will it be entitled to any return of any monies already paid.

11. Corporate Integrity Agreement

Contemporaneous with the execution of this agreement, TAP shall enter into a Corporate Integrity Agreement with the Office of Inspector General ("Inspector General") for the United States Department of Health and Human Services.

12. Corporate Authorization

TAP shall provide to the U.S. Attorney and the Court a certified copy of a resolution of the Board of Directors of TAP, affirming that the Board of Directors of TAP has authority to enter into the Plea Agreement and has (1) reviewed the Information in this case and the proposed Plea Agreement; (2) consulted with legal counsel in connection with the matter; (3) voted to enter into the proposed Plea Agreement; (4) voted to authorize TAP to plead guilty to the charges specified in the Plea Agreement; and (5) voted to authorize Thomas Watkins to execute the Plea Agreement and all other documents necessary to carry out the provisions of the Plea Agreement.

TAP agrees that a duly authorized corporate officer or member of the board of directors, and not an attorney, will appear on behalf of TAP and will enter the guilty plea and will also appear for the imposition of sentence.

13. Who is Bound by Agreement

This Agreement is binding upon the Attorney General of the United States, the Department of Justice, and all United States Attorneys on the matters as set forth in paragraph 4 but can not and does not bind the Tax Division of the U.S. Department of Justice or the Internal Revenue Service of the U.S. Department of the Treasury. TAP also understands that this agreement does not bind any state or local prosecutive authorities.

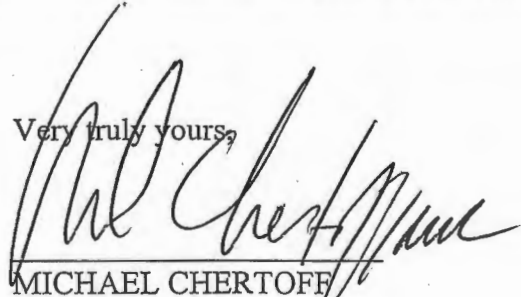
14. Complete Agreement

This letter, together with the attached Civil Settlement Agreement, the Civil Side Letter to TAP, the attached Limited Privilege Waiver Letter, and the attached Side Letters with Abbott Laboratories and Takeda Chemical Industries, Ltd., set forth the complete and only agreement between the parties relating to the disposition of this case. No promises, representations or agreements have been made other than those set forth in this letter, and the five attached and referenced documents. This Agreement supersedes prior understandings, if any, of the parties, whether written or oral, with the exception of those promises and representations set forth in the


attached documents. This Agreement can be modified or supplemented only in a written memorandum signed by the parties or on the record in court.

If this letter accurately reflects the Agreement between the U.S. Attorney and TAP, please have TAP sign the Acknowledgment of Agreement below. Please also sign below as Witness. Return the original of this letter to Health Care Fraud Chief Michael K. Loucks of the District of Massachusetts.

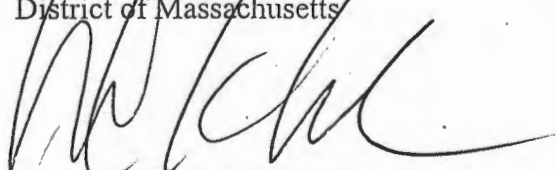
Very truly yours,



MICHAEL CHERTOFF
Assistant Attorney General
for the Criminal Division
United States Department of Justice



MICHAEL J. SULLIVAN
United States Attorney
District of Massachusetts



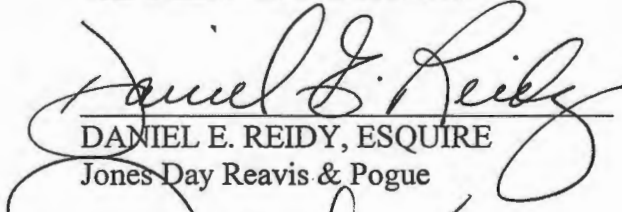
MICHAEL K. LOUCKS
Health Care Fraud Chief
District of Massachusetts

Corporate Acknowledgment of Plea Agreement

The Board of Directors has authorized me to execute this Plea Agreement and the attached Civil Settlement Agreement, as well as the attached Limited Privilege Waiver Letter, on behalf of TAP Pharmaceutical Products Inc. The Board has been well informed regarding these documents in their entirety, as well as the attached Side Letters with Abbott Laboratories and Takeda Chemical Industries, Ltd., and has discussed them fully with TAP Pharmaceutical Products Inc.'s attorney. The Board acknowledges that these documents fully set forth TAP's agreements with the United States. The Board further states that no additional promises or representations have been made to the Board by any officials of the United States in connection with this matter, other than those set forth in this plea agreement and in the attached Civil Settlement Agreement, the Civil Side Letter Ancillary thereto, the attached Limited Privilege Waiver Letter, and the attached Side Letters with Abbott Laboratories and Takeda Chemical Industries, Ltd.

H. THOMAS WATKINS
President
TAP Pharmaceutical Products Inc.

Dated: 9/28/01



DANIEL E. REIDY, ESQUIRE
Jones Day Reavis & Pogue

Dated: 9/28/01



JOSEPH F. SAVAGE, JR. ESQUIRE
Testa Hurwitz & Thibault, LLP